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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,446	06/22/2006	Takahiro Ueda	21581-00496-US	6380

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EXAMINER	
KATAKAM, SUDHAKAR	

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
09/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,446	UEDA ET AL.	
	Examiner	Art Unit	
	SUDHAKAR KATAKAM	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 10-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 10-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/18/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the application

1. Receipt of Applicant's request for continued examination filed on 22 April 2010 is acknowledged.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 April 2010 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Merck & Co., Inc** (GB 947,643) and applicants' acknowledged prior art in view of **Kijima et al** (US 4,061,660), **Kijima et al** (US 4,039,573), **Morita et al** (US 4,163,864) and WO 03/006409 & WO 03/006411 (see IDS dated 08/18/2010).

Merck & Co teaches preparation and purification of reduced coenzyme Q_{10} from the oxidized form of coenzyme Q_{10} in ethanol and adding excess of sodium borohydride in aqueous medium and the resulted yellow orange compound is diluted with water and the compound is extracted with petroleum ether. The petroleum extracts are washed with water and then dried, which results in crystallized form of reduced coenzyme Q_{10}, the pure hydroquinone of coenzyme Q_{10}. This may be recrystallized from alcohol-petroleum ether mixture. **Merck & Co** teachings also do not use chromatographic purification steps.

Applicants' specification acknowledges the impurities present in the reduced coenzyme Q_{10} such as oxidized coenzyme Q_{10}, reducing agents such as sodium borohydride, and known reducing agents such as zinc and vitamin C species [see page 1 of the specification].

The difference between the instant claims and the **Merck & Co** is that in the instant claims comprises washing crystals with water-soluble organic solvents and thereby remove a water-soluble impurities from the crystals, whereas **Merck & Co** teaches washing petroleum extract with water and then dried to get the pure crystals and this may be recrystallized with alcohol-petroleum ether mixture.

Washing and purifying crystals is a well known process in the art. It is desirable to use suitable solvents in which impurities get dissolved. **Merck & Co** is silent on the applicants' solvents; However, **Merck & Co** clearly suggested recrystallization with alcohol-petroleum ether mixture. It is a common practice to use suitable solvents for washing/purifying the crystals.

See the following prior art for washing coenzyme Q_{10}, in the analogous situation of purification of similar compounds, the crystals are washed with water soluble organic solvents.

Kijima et al (US 4,061,660) teach washing of crystals with diethyl ether [see Example 1].

Kijima et al (US 4,039,573) additionally discloses an analogous washing process where zinc is the catalyst [see Example 3].

Morita et al (US 4,163,864) also shows an analogous washing process, where methanol is used for washing [see Example 1].

WO 03/006409 and WO 03/006411 teach coenzyme Q10 is crystallized in a solution of alcohols and/or ketones, reduced coenzyme Q10 crystals having excellent slurry properties can be obtained [see abstract and also applicants submitted international search report].

In summary, **Merck & Co** teaches preparation and purification of reduced coenzyme Q_{10} from the oxidized form of coenzyme Q_{10} in ethanol and adding excess of sodium borohydride. Applicants' specification acknowledges the impurities present in the reduced coenzyme Q_{10}. An analogous prior art teaches

the use of water soluble organic solvents in washing the crystals to remove the impurities.

All the claimed elements were known in the prior art and one skilled person in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to have yielded predictable results to one of ordinary skill in the art at the time of the invention. In this case, in view of the above cited prior art, the washing step is with various solvents is very well established in the art.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to start with the **Merck and Co** teachings and combine the teachings of known solvents for the purification process, to achieve the instant claims with a reasonable expectation success. It is after all a simple washing to remove impurities using suitable solvents. The selection of a solvent is depends on the solubility of the impurities. Absent any showing of unusual and/or unexpected results, the art obtains the same effect on the purification of reduced coenzyme Q10. The expected result would be an improved purification of reduced coenzyme Q10 for the chemical industry.

Modifying such parameters is prima facie obvious because an ordinary artisan would be motivated to optimize the purification process to make the process more economical, since it is within the scope to exchange the solvents through a routine experimentation.

Response to Arguments

5. Applicant's arguments filed on 22 April 2010 have been fully considered but they are not persuasive.

Applicants argue that a skilled person in the art would not expect that water-soluble solvents are much more effective than water for removing water-soluble impurities.

The secondary references cited in the above rejection, already recognized the use of water-soluble solvents, such as methanol and ethanol, for washing crystalline coenzyme Q10, in order to remove the impurities from it.

With regard to applicants filed declaration, these solvents and their used in the purification of coenzyme Q10 are already established in the art [see above references cited in the above rejection].

Conclusion

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information

for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/
Examiner, Art Unit 1621